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July 30, 2009

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BY HAND

The Honorable Patti B. Saris
United States District Court for the
District of Massachusetts
John J. Moakley U.S. Courthouse
1 Courthouse Way
Boston, MA 02210

Re: *City of New York* v. *Abbott Laboratories, et al.*, MDL No. 1456
(Materials Requested Following FUL Tutorial)

Dear Judge Saris:

This letter will supplement the record on the FUL issues raised in the tutorial and summary judgment argument on June 8, 2009.

Following Dr. Addanki's testimony regarding how, in practice, CMS established FULs, you asked him whether he had his "very helpful chart for every single one of the 31 [FULs]." Defendants undertook to provide you with a complete set of Dr. Addanki's pricing arrays. *See* 7/8/09 Tr. at 38:2-14, and a copy of those pricing arrays is enclosed. Tab A contains the pricing arrays for the 23 out of 31 FULs for which lower published prices existed at the time CMS set the FUL and illustrates, as explained more fully in Dr. Addanki's June 30, 2009 Affidavit [Docket No. 113], that Ms. Gaston's *post hoc* "three WAC rule-of-thumb" cannot explain why CMS chose to disregard these lower published prices in 20 out of 23 cases. Tab B contains the pricing arrays for the 29 out of 31 FULs for which, as Dr. Addanki explained, the national pricing compendia published a lower price at some point while the FUL remained in effect and, yet, CMS declined to reduce the FUL.

We also feel compelled to respond to Ms. Cicala's letter of July 10, 2009, purporting to "make a correction to the record" concerning the number of CMS witnesses who have been deposed in this case. The depositions of many of those CMS witnesses who she claims were deposed in this case were not in fact cross-noticed in this case. *See, e.g.*, Notice of Deposition of Glenda Bailey (attached hereto as Exhibit A) (which shows that Ms. Bailey's deposition was noticed only in the case brought by the United States against Abbott and not cross-noticed in this case). More importantly though, ***only two individuals*** directly responsible for setting FULs were deposed (Sue Gaston and Gayle Sexton), and those depositions lasted less than a day in total. *See* Excerpts of the Gaston and Sexton Depositions (attached hereto as Exhibit B). Ms. Sexton was not, for example,

deposed over two days as Ms. Cicala's letter represents. *Id.* In fact, CMS denied defendants' request to take the depositions of the other current and former CMS employees who were directly responsible setting FULs during the relevant time, citing *United States ex rel. Touhy* v. *Ragen*. *See* Exhibit C hereto (March 20, 2008 letter denying defendants' request to depose Cindy Bergin and Peter Rodler).

Respectfully submitted,

John T. Montgomery

Enclosures

cc: Joanne M. Cicala, Esq.
All Counsel of Record (by LNFS)

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Chief Magistrate Judge Marianne B. Bowler

NOTICE OF DEPOSITION OF GLENDA BAILEY

PLEASE TAKE NOTICE that, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Abbott Laboratories, by its undersigned attorneys, will take the deposition of Glenda Bailey. Ms. Bailey is being deposed in response to Abbott's Notice of Deposition of one or more persons designated by the United States to testify regarding the United States' responses to subpoenas issued in the Lupron MDL and the AWP MDL.

The deposition will take place before a notary public, or any other officer authorized to administer oaths, at the office of Hogan & Hartson LLP, 111 South Calvert St., Baltimore, MD, on March 20, 2007, beginning at 9:00 a.m. and continuing on successive days as necessary. Such deposition will be recorded by stenographic and/or sound and visual means.

The deposition is being taken for the purposes of discovery, for use at trial, and for such other purposes as permitted under the Federal Rules of Civil Procedure.

Dated: March 8, 2007

/s/ R. Christopher Cook
James R. Daly
Tina M. Tabacchi
Brian J. Murray
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 782-3939
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R. Christopher Cook
David S. Torborg
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Facsimile: (202) 626-1700

Counsel for Defendant Abbott Laboratories, Inc.

CERTIFICATE OF SERVICE

I, R. Christopher Cook, an attorney, hereby certify that I caused a true and correct copy of the foregoing NOTICE OF DEPOSITION OF GLENDA BAILEY to be served upon be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 8th day of March, 2007.

/s/ R. Christopher Cook
R. Christopher Cook

EXHIBIT B

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION
PRICE LITIGATION	)	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)	
U.S. ex rel. Ven-a-Care of	)	Judge Patti B. Saris
the Florida Keys, Inc.	)	
v.	)	Chief Magistrate
Abbott Laboratories, Inc.,	)	Judge Marianne B.
No. 06-CV-11337-PBS	)	Bowler

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(cross captions appear on following pages)

Videotaped deposition of SUE GASTON

Volume II

Washington, D.C.

Wednesday, March 19, 2008

9:00 a.m.

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their FDB file the first week of May. The file contains an indicator which denotes the 'true AWP prices' for those 400 drugs that were identified on the price list states received from the attorney general's office. I will keep you advised on this issue and share any additional information received. Please remember that any changes in your reimbursement methodology must be reflected in your state plan."

Do you see that?

A. Yes.

Q. And he was forwarding an e-mail that you had written to individuals in the HCFA regional offices, correct?

A. This looks like it was to folks at the state. You're talking about the May 11th?

Q. I'm talking about the e-mail that you sent on April 25th, 2000. Individuals in the distribution line are individuals in the HCFA regional offices, correct?

A. Correct. Oh, he copied. Okay. Correct.

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Q. And you gave a brief summary in your e-mail, correct?

A. Yes.

Q. Of the true AWP prices that were being placed on 400 drugs, correct?

MS. MARTINEZ: Objection, form.

A. Correct. The First Databank settlement.

Q. And you stated amongst other things, "By way of background, there is a qui tam False Claims Act lawsuit files against more than 20 drug manufacturers which is still partially under seal." Do you see that?

A. Correct.

Q. And that's consistent with your recollection that the DOJ/NAMFCU AWP effort was one that was coming out of litigation --

A. Yes.

Q. -- correct?

So that effort to provide more accurate AWPs was something that was instigated by the Department of Justice, correct?

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MS. MARTINEZ: Objection, form.

A. That's what it appears.

MR. TORBORG: Ms. Gaston, that's all the questions I have for you at this time. I reserve the right to ask some follow-up questions. But we're done. I thank you for your time.

THE WITNESS: Okay.

THE VIDEOGRAPHER: Off the record at 11:41.

(Recess.)

THE VIDEOGRAPHER: On the record at 11:53.

EXAMINATION BY COUNSEL FOR WARRICK PHARMACEUTICALS, SCHERING-PLOUGH CORPORATION AND SCHERING CORPORATION

BY MR. BUEKER:

Q. Good morning, Ms. Gaston. My name is John Bueker. I'm here on behalf of Warrick Pharmaceuticals, Schering-Plough Corporation and Schering Corporation. And we all are defendants

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in the New York counties case. And I'm going to focus my questioning on that case. There have been nine drugs for which FULs have been established that have been singled out for kind of focused discovery.

And a lot of what I want to do today is use I think some of the printouts from the FUL application that maybe you looked at to refresh your recollection for the deposition and kind of walk through the mechanics of how FULs are set to kind of drill down and see if we can't better understand that process, is a lot of what I want to do today.

A. Okay.

Q. But I just want to before we delve into that make sure that we have a common understanding with regard to the chronology here for a second. As I understand it, from 1991 to 2003 you were one of the individuals at CMS who was responsible for setting the FULs; is that correct?

A. Correct.

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thought was appropriate to incorporate into the process of setting FULs you incorporated that information?
A. For the updates, yes.
Q. And then annually or some other period of time, at least you began annually at the beginning, there were these systematic updates of the entire list?
A. Correct.
Q. Separate and apart from that, what triggered the decision to actually add a new drug to the list?
A. Most of the time it came out on a new run that we would do. So if we're looking at updating the whole entire FUL list, that's when the new drugs would show up.
Q. Let me see if I understand. So the FUL system -- when you do the update of the entire list, the FUL system would go back to Orange Book and identify all the drugs that were eligible and also pull in the published prices. So at that time if a drug had gone generic and was now --

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met the minimum criteria, it would get pulled in and you would at least get one of the printouts we've been looking at like Exhibit 18?
A. Correct.
Q. And then you begin a manual review process at that point to decide whether or not to set a FUL?
A. If it was necessary. It might have enough information we wouldn't have to do a manual review.
Q. Okay. And there may also have been other instances in which you got the information and decided even though the drug met the minimum criteria in the regulation, for some other reason it wouldn't result in a cost savings or the FUL that would be derived on the basis of the published prices would be too low, you might decide not to set a FUL at that point even though it was eligible?
A. Yes, if there was a reason not to set it.
Q. Okay. It sounds like in terms of

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setting brand-new FULs at the very least they would have been picked up as a part of the complete or the entire update process?
A. Correct.
Q. And at that point, just like with any of the other FULs, CMS would have made a determination as to whether it made sense to add a FUL, whether it was reasonable to add a FUL at that time?
A. Correct.
Q. Can you remember instances in which a drug was new, came on -- a new drug was identified as a result of the annual update process and CMS decided not to set a FUL?
A. I can't remember that.
Q. You can't remember specific examples?
A. Correct.
Q. But don't doubt that it happened?
A. It could have happened.
MS. MARTINEZ: Objection, form.
Q. Is there anything else other than having the annual update or receiving information

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from industry sources that would have caused CMS in your time period, '91 and 2003, to update the FUL list?
A. That's all I can think of.
MR. BUEKER: Okay. Well, that's all I have.
THE WITNESS: Okay.
MR. BUEKER: I appreciate your time.
THE WITNESS: You're welcome.
MR. BUEKER: I think some of the others here may still have questions.
THE VIDEOGRAPHER: This is the end of tape 4. Off the record at 355.
(Recess.)
THE VIDEOGRAPHER: This is the beginning of tape 5 in the deposition of Ms. Gaston. On the record at 3:57.

EXAMINATION BY COUNSEL FOR DEY, INC., DEY, L.P. AND MYLAN
BY MS. REID:
Q. Good afternoon. My name again is Sarah

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION NO.
PRICE LITIGATION	)	01-CV-12257-PBS

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THIS DOCUMENT RELATES TO:)

The City of New York v. Abbott Labs., et al.)

(S.D.N.Y. No. 04-CV-06054))

County of Suffolk v. Abbott Labs., et al.)

(E.D.N.Y. No. 03-CV-229))

County of Westchester v. Abbott Labs., et al.)

(S.D.N.Y. No. 03-CV-6178))

County of Rockland v. Abbott Labs., et al.)

(S.D.N.Y. No. 03-CV-7055))

[Caption continues on Next Page])

Washington, D.C.

Monday, May 20, 2008

9:30 a.m.

VIDEOTAPED DEPOSITION OF GAIL SEXTON

P R O C E E D I N G S

(9:31 a.m.)

THE VIDEOGRAPHER: In the United States District Court for the District of Massachusetts, In Re: Pharmaceutical Industry Average Wholesale Price Litigation, Consolidated New York Counties, Case Number 01-CV-12257 PBS, this is the deposition of Gail Sexton.

Today's date is May 20th 2008. The location of the deposition is Ropes & Gray, 700 12th Street, N.W., Washington, D.C.

Will counsel please identify yourselves and state whom you represent?

MR. BUEKER: Good morning, Ms. Sexton. My name is John Bueker. I'm here at Ropes & Gray. I'm appearing on behalf of Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation.

MR. FLESSNER: Good morning, Ms. Sexton. My name is Mark Flessner. I'm with Sonnenschein, Nath & Rosenthal in Chicago and I represent Ethex.

EXAMINATION BY COUNSEL FOR SCHERING-PLOUGH CORPORATION, SCHERING CORPORATION AND WARRICK PHARMACEUTICALS CORPORATION

BY MR. BUEKER:

Q. Good morning, again, Ms. Sexton. Would you just state and spell your name for the record, please?

A. Yes. Gail, G-a-i-l, Sexton, S-e-x-t-o-n.

Q. And how are you presently employed?

A. I'm employed as a health insurance specialist with the Centers for Medicare and Medicaid Services in Baltimore, Maryland.

MS. HANSCOM: Excuse me. I cannot hear the witness.

MS. SALZMAN: Nor can I.

(Discussion off the record.)

BY MR. BUEKER:

Q. Perhaps we could started again. Could you state and spell your name for the record, please?

A. Yes. My name is Gail Sexton, G-a-i-l

UNITED STATES OF AMERICA

BY MR. FAUCI:

Q. Ms. Sexton, if you saw a price published in the compendia which appeared to you to be an outlier in that it was significantly lower than other prices, I believe you testified that you might call the supplier to verify that the price was actually available; is that correct?

A. Yes.

Q. And if the answer to that question is yes, if you verified that the drug was available at that price, would you use that price to set the FUL?

A. Yes.

MR. FAUCI: That's all.

MR. BUEKER: I have nothing further. Does anyone on the phone have any further questions for this witness?

THE VIDEOGRAPHER: This deposition concludes at 1:05 and consists of two tapes.

(Whereupon, at 1:05 p.m. the

videotaped deposition was adjourned.)

_____

GAIL SEXTON

Subscribed and sworn to and before me this _____ day of _____, 20____.

_____

Notary Public

EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

MAR 20 2008

John P. Bueker
Ropes & Gray LLP
One International Place
Boston, MA 02110-2624

Re: Request for testimony in City of New York v. Abbott Laboratories, Inc.; MDL No. 1456; 01-CV-12257-PBS. (D. Mass.)

Dear Mr. Bueker:

I write in response to your letter to Kerry Weems, Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services (HHS) and James C. Stansel, Acting General Counsel for HHS, in which you request the deposition testimony of current CMS employees Gail Sexton and Cindy Bergin (the former Cindy Pelter) and a former CMS employee, Peter Rodler, in the above-referenced litigation to which the government is not a party.

As current and former employees of CMS, Ms. Sexton, Ms. Bergin and Mr. Rodler are covered by the agency's "Touhy regulation," 45 C.F.R. Part 2. The HHS Touhy regulation prohibits HHS employees and former employees from providing testimony or producing documents concerning information acquired in the course of performing official duties unless "authorized by the Agency head . . . based on a determination by the Agency head, after consultation with the Office of the General Counsel, that compliance with the request would promote the objectives of the Department." 45 C.F.R. § 2.3. See United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951); Moore v. Armour Pharm. Co., 927 F.2d 1194 (11th Cir. 1991). The CMS Administrator has delegated the authority to make these determinations to the Deputy Administrator, Regional Administrators, Center Directors, and Office Directors. Pursuant to this delegation, I am responsible for deciding whether to approve your request.

Your request for testimony is made as part of litigation in, City of New York v. Abbott Laboratories, Inc.; MDL No. 1456; 01-CV-12257-PBS (D. Mass.), a matter to which the government is not a party. However, the case is one of several cases that are part of a multi-district litigation (MDL) currently before the United States District Court for the District of Massachusetts. The federal government has also filed a complaint against Abbott Laboratories, Inc. and the case, United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., MDL No. 1456; No. 06-CV-11337-PBS (D. Mass), is also part of the MDL. As part of discovery in the government's case, several CMS employees have been and continue to be deposed on multiple days. Those employees include Larry Reed, Technical Director, Pharmacy Team, with general oversight of the federal upper limit (FUL) program; Deirdre

Duzor, Director, Pharmacy Team; and Sue Gaston, formerly lead Pharmacy Team analyst for the FUL program and currently Team Lead for Dispute Resolution of the Medicaid Drug Rebate Program. Also, as part of discovery in the government's case, CMS has produced current and historical documents demonstrating the establishment of FULs and how FULs were calculated for certain multi-source drugs. CMS has also responded to specific discovery requests concerning the calculation of the FULs. Everything produced by CMS as part of the government's litigation is available to all the plaintiffs and defendants in the MDL, including the Warrick Defendants. Considering the prior and continuing discovery regarding FULs in the government's case, I have decided to deny testimony for Peter Rodler and Cindy Bergin because I believe that such testimony would not promote the objectives of HHS as it is duplicative of previous discovery responses, including prior deposition testimony.

However, I believe that it would promote the interests of the HHS to allow Gail Sexton, the current operator of the FUL program, to testify on the development, to the extent there has been such, of FULs for the following drugs: enalapril maleate (20 mg tablet), lorazepam (1 mg tablet), klonopin (0.5 mg tablet), albuterol (90 mcg inhaler and 0.83 mg/ml solution), metropolol (100 mg tablet), cefadroxil (500 mg tablets and capsulate), ranitidine (150 mg tablet), and isosorbide mononitrate (60 mg tablet).

HHS' approval of this request as to Gail Sexton should not be construed as an endorsement by HHS of any statements which Ms. Sexton may make in a deposition. HHS reserves the right to correct any inaccuracies that may occur by filing a brief with the court or by otherwise correcting the record in an appropriate manner.

If you have any questions about this decision, please contact Brian Kelley, of the Office of the General Counsel at (202) 205-8702.

Sincerely,

Dennis G. Smith
Director,
Center for Medicaid and State Operations